TMTI Industry Day
Dallas Texas
18 November 2009

Plenary Session (Pegasus B)
(Moderator: Weaver)

Time	Event	Speaker
0900-0905	**Welcome and Overview**	
0905-0940	**Chemical Biological Defense Program Overview** *Mr. Jean Reed, Deputy Assistant to the Secretary of Defense (Chemical and Biological Defense and Chemical Demilitarization)*	**Mr. Reed**
0940-1015	**Integrated Medical Countermeasures Biodefense Portfolio** *Carol Linden, Ph.D., Principal Deputy Director of Biomedical Advanced Research and Development Authority (BARDA)*	**Dr. Linden**
1015-1030	**Break**	
1030-1100	**FDA Regulatory Framework** *Dr. Frederic Marsik, Ph.D., Clinical Microbiology Team Leader Office of Antimicrobial Products (OAP) - FDA*	**Dr. Marsik**
1100-1130	**TMTI Overview** *Mr. David Hough, TMTI Director*	**Mr. Hough**
1130-1145	**Medical Countermeasures Portfolio** *Ms. Heather Wargo, TMTI Medical Countermeasures Portfolio Manager*	**Ms. Wargo**
1145-1200	**TMTI Technologies Portfolio** *Mr. David Klaasse, Technologies Product Manager*	**Mr. Klaasse**
1200-1330	**Lunch**	

Plenary Session
Speaker Biographies

Jean Reed

Jean D. Reed, is the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization, in the Office of the Assistant to the Secretary of Defense (Nuclear and Chemical and Biological Defense Programs). As Deputy Assistant, Mr. Reed has responsibility for oversight of chemical and biological defense programs throughout the Department of Defense and destruction of the United States stockpile of lethal chemical agents and munitions. He was appointed to the Senior Executive Service on December 27, 2005.

Mr. Reed comes to this position after 15 years as a professional staff member of the Committee on the Armed Services, U.S. House of Representatives, where he had principal responsibility for staff oversight of Navy research and development, Defense-wide science and technology, chemical-biological defense, and chemical weapons demilitarization programs. He was a principal member of the Committee staff team on the Persian Gulf War. He was also principal staff member for the Committee's special inquiry into the chemical and biological threat and co-authored the inquiry's report, "Countering the Chemical and Biological Weapons Threat in the Post-Soviet World," published in February 1993.

Carol Linden, Ph.D

Dr. Linden currently serves as the Principal Deputy Director of the Office of the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services. Her duties include oversight of advanced development and acquisition programs for Project BioShield medical countermeasures for CBRN threats as well as pandemic influenza vaccines, drugs, diagnostics and infrastructure. From October 2006 through April 2008 she also served as the Acting Director of BARDA, responsible for a doubling in the size of the office and implementation of the legislation that established the office.

Dr. Linden previously served as the Senior Scientist for the Office of Research and Development in the Science and Technology Directorate of the Department of Homeland Security, overseeing treaty and regulatory compliance as well as international collaborations. Immediately prior to this position, she served as Deputy Director of the Office of Research Programs. Prior to joining the Department of Homeland Security, Dr. Linden was the Scientific Director for the Defense Threat Reduction Agency (DTRA) Chemical and Biological Defense Directorate from mid-2003 until spring of 2004. Before her detail to DTRA, she served as the Director for the Department of Defense Medical Chemical and Biological Defense Research Programs for over 3 years, managing all aspects of the joint services medical Chemical and Biological Defense Program. She chaired the tri-service Joint Technology Coordinating Groups for medical chemical and medical biological defense on behalf of the Armed Services Biomedical Review and Evaluation Board. Dr. Linden served a critical function in coordinating the working relationship between the technology base and advanced development, facilitating the transition of candidate vaccines, diagnostic technologies and therapies to the developer.

Dr. Linden obtained her bachelor's degree in biology from Bryn Mawr College, and a Ph.D. from the University of California Los Angeles in molecular biology. She conducted postdoctoral research at the California Institute of Technology and University of Maryland prior to joining the research staff at the U.S. Army Medical Research Institute of Infectious Diseases, where she subsequently served as the Chief, Research Plans and Programs.

Fred Marsik

Frederic Marsik, Ph.D., ABMM , is the Microbiology Team Leader, Division of Antiinfective and Ophthalmology Products, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, MD

Dr. Marsik has been a Clinical Microbiology Reviewer of antimicrobial drug products for the FDA for the past 13 years. During that time he has been a microbiology team leader in antiviral drug products, and generic drug products. Currently he is a microbiology team leader in the Division of Antiinfectives and Ophthalmology Products (DAIOP) in the Office of Antimicrobial

Products (OAP), Center for Drug Evaluation and Research (CDER). In addition to reviewing antimicrobial submissions he is involved in counter bioterrorism efforts, the writing of clinical and microbiology guidances and serves as a microbiology consultant to a variety of other FDA divisions. Prior to joining the FDA Dr. Marsik worked for a large culture media and diagnostic manufacturer as the director of media research where he lead the effort to develop the first radiation sterilized media for the environmental sampling of pharmaceutical manufacturing environments. He has also been the director of clinical microbiology laboratories at several large health care facilities. Dr. Marsik is active on a variety of internal FDA committees, as well as committees for outside organizations (e.g. USP, CDISK). He is an FDA advisor to the antimicrobial susceptibility test subcommittee of the Clinical Laboratory Standards Institute (CLSI) and participates on a variety of other CLSI subcommittees. Dr. Marsik did his undergraduate work at Lebanon Valley College, Annville, PA and his graduate work at the University of Missouri School of Medicine, Columbia, MO. He did his post-doctoral work in clinical microbiology and infectious disease at Hartford Hospital in Hartford, CT. He has a variety of publications in journals and books.

David Hough

Mr. David Hough is the Director of TMTI. Mr. Hough is a career naval officer with over 28 years of service before retiring and joining the Defense Contract Management Agency where he successfully oversaw the largest reorganization of a Defense Agency ever attempted. Since joining DTRA, he has served as Senior Acquisition Analyst for TMTI, Director of the Business Execution Office and most recently as Director of TMTI. Under his direction, TMTI has had two Investigational New Drug applications accepted with a number of others to be filed in the near future.

Heather Wargo

Ms. Heather Wargo, a microbiologist with DTRA, serves as the Medical Countermeasures Portfolio Manager for TMTI. She is responsible for a team of scientists and project managers dedicated to strategic planning, management, and execution of medical product developments for emerging and genetically engineered biothreats spanning basic research through FDA licensure.

Prior to joining TMTI, Ms. Wargo has held two positions within DTRA prior to joining TMTI, Senior S&T Manager within the Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) Medical Division, and Program Manager for JSTO-CBD Acquisition Support.

David Klaasse

Mr. David A. Klaasse currently manages the TMTI Technologies Portfolio. The Technologies Portfolio consists of forty projects with the goal of developing platform technologies to support rapid response to an attack by an emerging or genetically engineered biological agent. Prior to joining DTRA, Mr. Klaasse served over 20 years in the US Navy. While in the Navy, Mr. Klaasse flew aircraft carrier based F-14 "Tomcats" on numerous overseas deployments including combat operations in Operations Desert Storm, Desert Strike and Southern Watch. Between deployments, he graduated from the Navy's Fighter Weapons School (Topgun) and the US Naval Test Pilot School. Joining the Navy's acquisition corp, Mr. Klaasse managed Integrated Product Teams within the National Reconnaissance Office and the F-35 Joint Strike Fighter Program Office. Mr. Klaassee joined TMTI shortly after retiring from the US Navy in 2008.

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Break Out Session 1: Taming the Animal Rule (Pegasus B)
(Moderator: Moore)

Time	Event	Speaker
1330-1340	**Welcome and Overview** *Ms. Heather Wargo, TMTI Medical Countermeasure Portfolio Manager, CBDP/DoD and Session Co-Chair* *Mr. Mike Bailey, Biodefense Analyst, Tauri Group and Session Co-Chair*	**Ms. Wargo** **Mr. Bailey**

Part I: Government Assessment for Long Term Solution

1340-1400	**Animal Study Queue Evaluation Team** *Dr. Judy Hewitt, Chief, Biodefense Research Resources Section OBRA/DMID/NIAID/NIH/DHHS and ASQE Co-Chair*	**Dr. Hewitt**
1400-1420	**NBCAPD - Concepts and Planning** *LTC James Kotersky, DVM, PhD, Director, USAMRMC Partnership Support Office*	**LTC Koterski**
1420-1440	**NAS Study: Animal Models for Assessing Countermeasures to Bioterrorism Agents** *Dr. Rick Jaffe, Senior Medical Advisor to the DATSD(CBD/CD), ANSER, Inc*	**Dr. Jaffe**
1440-1450	**Break**	
1450-1500	**TMTI's Animal Model Working Integrated Process Team** *Mr. Mike Bailey, Biodefense Analyst, Tauri Group and WIPT Chair*	**Mr. Bailey**
1500-1540	**Panel Discussions** *Panel composed of topic presenters and Dr. Frederic Marsik, FDA representation*	
1540-1610	**Break**	

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Break Out Session 1: Taming the Animal Rule

Part II: Near Term Solutions for Current Product Pipeline

Time	Event	Speaker
1610-1630	**Partnering with USAMRIID** *Dr. Mark Dertzbaugh, Chief, Business Plans & Programs Office, USAMRIID*	**Dr. Dertzbaugh**
1630-1700	**Doing Business with NIAID** *Ms. Nancy Boyd, Chief, Extramural Biodefense Facilities Section Office OBRA/DMID/NIAID/NIH/DHHS*	**Ms. Boyd**
1700-1710	**Break**	
1710-1730	**A Crack of the Whip: Experience Seeking Licensure Under the Animal Rule** *Dr. Dennis Hruby, Chief Scientific Officer, SIGA Technologies Inc.*	**Dr. Hruby**
1730-1810	**Panel Discussion** *Panel composed of topic presenters and Dr. Frederic Marsik, FDA representation*	
1810-1820	**Next Steps**	

Break Out Session 1: Taming the Animal Rule
Speaker Biographies

Ms. Heather Wargo

Ms. Heather Wargo, a microbiologist with DTRA, serves as the Medical Countermeasures Portfolio Manager for TMTI. She is responsible for a team of scientists and project managers dedicated to strategic planning, management, and execution of medical product developments for emerging and genetically engineered biothreats spanning basic research through FDA licensure. Prior to joining TMTI, Ms. Wargo has held two positions within DTRA prior to joining TMTI, Senior S&T Manager within the Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) Medical Division, and Program Manager for JSTO-CBD Acquisition Support.

Mr. Michael Bailey

Mike Bailey is a BioDefense Analyst for the Tauri Group, supporting the Transformational Medical Technologies Initiative (TMTI). As the senior subject matter expert for animal model development, Mr. Bailey provides technical analysis and program management support on drug development and animal modeling projects. Mr. Bailey joined the TMTI team following a career in biodefense research including three years at the Vaccine Research Center at the National Institutes of Health, and five years at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) working primarily on filovirus vaccine development projects. Mr. Bailey earned a BS at the University of Pittsburgh, a MS from Johns Hopkins University, and is currently a graduate student in Public Policy at George Mason University.

Part I: Government Assessment for Long Term Solution

Dr. Judy Hewitt

Dr. Hewitt is Chief of the Research Resources Section in the Office of Biodefense Research Affairs, DMID/NIAID. A major resource within her group is the "In Vitro and Animal Models for Emerging Infectious Diseases and Biodefense" program, which provides NIAID/DMID with contract capabilities in antimicrobial screening and preclinical and efficacy testing in animals, particularly for biodefense pathogens. The primary focus of these capabilities thus far has been animal model development and testing, as animal models are a critical bottleneck for biodefense countermeasures. The second resource in her group is the Biodefense and Emerging Infections Resources Repository, which serves the infectious disease research community by acquiring, generating, characterizing, storing and distributing reagents to support basic research and the development of diagnostic tests, vaccines and therapies for infectious diseases. Dr. Hewitt earned her Ph.D. from Johns Hopkins University and completed post-doctoral fellowships at NICHD and the Cleveland Clinic Foundation before taking faculty-level positions at the University of Maryland and NIAID, where she ran transgenic and knockout mouse facilities focused on developing models for immunological studies.

LTC James Koterski, DVM PhD DACVPM

LTC "Nick" Koterski is a Veterinary Comparative Medicine Officer and has served in the Field Operations Branch of the Diagnostic Systems Division at USAMRIID, with the Force Health Protection Branch of the Medical Affairs Division at USAMMDA, and is now with the Chem/Bio Partnership Support Directorate of MRMC.

Dr. Rick Jaffe

Dr Rick Jaffe: Dr Jaffe has been the Senior Medical Advisor in support of OSA (CBD & CDP) ANSER Inc since March 2006. He received his BS degree in Microbiology from the University of Maryland in 1983, His MS in human genetics from George Washington University in 1989 and his PhD MT(ASCP) from Virginia Commonwealth University in 1995. He has written and researched extensively in the area of medical counter measures and is here today to talk about Animal Models for Assessing Countermeasures to Bioterrorism Agents.

Mr. Mike Bailey

See description above

Dr. Frederic Marsik

Frederic Marsik, Ph.D., ABMM , is the Microbiology Team Leader, Division of Antiinfective and Ophthalmology Products, Center for Drug Evaluation and Research, Food and Drug Administration, Silver Spring, MD

Dr. Marsik has been a Clinical Microbiology Reviewer of antimicrobial drug products for the FDA for the past 13 years. During that time he has been a microbiology team leader in antiviral drug products, and generic drug products. Currently he is a microbiology team leader in the Division of Antiinfectives and Ophthalmology Products (DAIOP) in the Office of Antimicrobial

Products (OAP), Center for Drug Evaluation and Research (CDER). In addition to reviewing antimicrobial submissions he is involved in counter bioterrorism efforts, the writing of clinical and microbiology guidances and serves as a microbiology consultant to a variety of other FDA divisions. Prior to joining the FDA Dr. Marsik worked for a large culture media and diagnostic manufacturer as the director of media research where he lead the effort to develop the first radiation sterilized media for the environmental sampling of pharmaceutical manufacturing environments. He has also been the director of clinical microbiology laboratories at several large health care facilities. Dr. Marsik is active on a variety of internal FDA committees, as well as committees for outside organizations (e.g. USP, CDISK). He is an FDA advisor to the antimicrobial susceptibility test subcommittee of the Clinical Laboratory Standards Institute (CLSI) and participates on a variety of other CLSI subcommittees. Dr. Marsik did his undergraduate work at Lebanon Valley College, Annville, PA and his graduate work at the University of Missouri School of Medicine, Columbia, MO. He did his post-doctoral work in

clinical microbiology and infectious disease at Hartford Hospital in Hartford, CT. He has a variety of publications in journals and books.

Part II: Near Term Solutions for Current Product Pipeline

Dr. Mark Dertzbaugh

Dr. Dertzbaugh is the Chief of Business Plans and Programs at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), which is the Department of Defense's (DOD) lead laboratory for medical biological defense research. He is responsible for planning and managing the institute's portfolio of projects and business relationships, which has increasingly involved collaborations with industry and other federal agencies. USAMRIID's capabilities and experience related to Select Agents and animal models has made it a key player in "Taming the Animal Rule".

Dr. Dertzbaugh has a Ph.D. in Microbiology & Immunology, and has published numerous papers in the field of vaccine research. He began his career at USAMRIID in 1991, working on several vaccine-related R&D projects. In 1996, he joined the DOD's Joint Vaccine Acquisition Program (JVAP) as Product Manager for the Venezuelan Equine Encephalitis virus infectious clone candidate. He also served as the Contracting Officer's Technical Representative for the BioPort anthrax vaccine contract. In 1998, Dr. Dertzbaugh returned to USAMRIID to become Chief of the Respiratory Immunology Branch and worked on characterization of host responses to threat agents in the lung. In 2000, he became Chief of Research Programs at USAMRIID where he has been responsible for conducting the planning and execution of the institute's research portfolio. Since 2004, Dr. Dertzbaugh has been the Chief of Business Plans & Programs at USAMRIID and has played a key role in efforts to transform the institute including strategic planning, organizational restructuring, portfolio management, and enterprise-wide resource planning to meet future needs in biological defense R&D.

Ms. Nancy Boyd

Nancy Boyd is the Chief of the Extramural Biodefense Facilities Section in the Office of Biodefense Research Affairs at the National Institute of Allergy and Infectious Diseases, NIH. She has been leading the Team of NIAID Program Officers that oversee the National and Regional Biocontainment Laboratories construction grants as well as other biodefense related initiatives since October, 2002. Prior to joining NIAID, Ms. Boyd was a Project Officer for the Division of Engineering Services, NIH from 1987 – 2002 where she managed the design and construction of biomedical research laboratory facilities. Prior to her employment with NIH, Ms. Boyd worked in the Public Works Branch at the Naval Research Laboratory from 1984 – 1987 where she was responsible for facilities design and design review. Ms. Boyd has a Bachelor of Science degree in Civil Engineering from the University of Maryland.

Dr. Dennis Hruby

Dr. Hruby is SIGA's Chief Scientific Officer and a Professor of Microbiology at Oregon State University. He is a member of the American Society for Virology, the American Society for

Microbiology and the American Academy of Microbiology. He has received numerous honors and awards, including the OHSU Foundation Discovery Award, the F. A. Gilfillan Award for Career Achievement, the Sigma Xi Research Award and being named the OSU Alumni Distinguished Professor. Dr. Hruby specializes in virology and microbial pathogenesis research, with an emphasis on poxvirology. Throughout his career, Dr. Hruby has published over 200 peer-reviewed journal articles and is a sought after speaker with more 350 abstracts and presentations to his credit. He has been actively involved with biodefense research for the past decade, having served on numerous federal advisory panels and the W.H.O. Smallpox Advisory Group. Dr. Hruby has been continuously funded by the National Institutes of Health since 1983 and has served on numerous grant panels, including his present assignment on the Drug Discovery and Antimicrobial Resistance study section. Currently, Dr. Hruby is the Principal Investigator (PI) on federal grants and contracts in excess of $130 million and is the PI on SIGA's RFP contract submission to supply smallpox antiviral to the Strategic National Stockpile

Dr. Frederic Marsik

See description above

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Break Out Session 2 (Gaston A & B)
(Moderator: McCormick)

Time	Event	Speaker
	Target Identification	
1330-1400	**TMTI Target Identification Workshop** *Mr. Adekunle Famodu, TMTI Program Manager* *Dr. Julia Scheerer, TMTI Subject Matter Expert* *Mr. David Klaasse, Technologies Product Manager* • Definition of Target ID • Identify the type of work needed by the RFI	**Mr. Famodu** **Dr. Scheerer** **Mr. Klaasse**
1400-1425	**RFI Review** • Comments on the RFI	**Mr. Famodu**
1425-1440	**Break**	
1440-1540	**Group Discussion** • What is a validated target? • What techniques methods, procedures, and protocols are needed for identification of therapeutic pathways and targets and how are they validated? • What are the inputs and outputs of target ID?	
	Medical Countermeasures Discovery	
1610-1625	**Countermeasures Discovery Technologies Team** *Dr. Nate Adams, TMTI Program Manager* *Mr. David Klaasse, Technologies Product Manager*	**Dr. Adams** **Mr. Klaasse**

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Break Out Session 2 (Gaston A & B)
(Moderator: McCormick)

Time	Event	Speaker
1625-1640	**RFI Review**	**Dr. Adams**
1640-1650	**Break**	
1640-1810	**Group Discussion** • What are the ways to shorten the timeline? • What other innovative and effective techniques could reduce time and risks? • What are the inputs and outputs of the counter measure process?	

Break Out Session 2: Understanding Requirements by Performers and TMTI Speaker Biographies

Target Identification

Mr. Adekunle Famodu

Mr. Famodu is a Program Manager primarily responsible for the development of the Target Identification arm of the Rapid Response Capability within the Technologies Development Portfolio of the Transformational Medical Technologies Initiative (TMTI), Chemical and Biological Defense Program, Defense Threat Reduction Agency, Fort Belvoir, Virginia. Additional responsibilities include the management of the DTRA/DARPA joint Accelerated Manufacturing Platform program and the management of TMTI funded projects at DSTL (UK)

Prior to his reassignment to the TMTI Technologies Development Portfolio, He was responsible for the project management of a multimillion dollar portfolio of contracts aimed at producing medical therapeutic countermeasures against known and emerging biological threat agents as well as potential bio engineered threats.

He began his Civil Service Career with the Department of Homeland Security in 2002 and joined the Department of Defense as a Civilian in 2005, as a Treaty Compliance Officer working on U.S Government compliance with the Chemical Weapons Convention to include active verification at Chemical Weapons Demilitarization plants.

He served 8 years in the U.S. Army Reserves as a Chemical, Biological, Radiation and Nuclear (CBRN) Specialist, with deployments in support of Operation Enduring Freedom as a member of the Combined Joint Special Operations Task Force – Afghanistan and Horn of Africa in 2003/2004.

He earned an Associates of Arts and Sciences Degree from Montgomery College, Takoma Park, Maryland, a Bachelor of Science in Biology from Howard University, Washington DC and a Masters Degree in Business Administration from the University of Baltimore's Merrick School of Business, Baltimore, Maryland.

Dr. Julia Scheerer

Dr. Scheerer is a subject matter expert (SME) with Bull and Associates / The Tauri Group. She provides technical assistance for the development of the Target Identification arm of the Rapid Response Capability within the Technologies Development Portfolio of the Transformational Medical Technologies Initiative (TMTI), Chemical and Biological Defense Program, Defense Threat Reduction Agency, Fort Belvoir, Virginia. Additional responsibilities include technical assistance with Medical Countermeasure Evaluation projects, assessment of research proposals, and preparation of requirements for new projects.

Prior to joining Bull and Associates / The Tauri Group, she completed a Master of Science degree in Bioscience Management at George Mason University, Fairfax, VA.

Previously, she managed a molecular genetics laboratory and performed scientific research in environmental genetic toxicology, mechanisms of genetic mutation and repair, immunogenetics, and protein epitopes of metabolic disease.

Dr. Scheerer earned her Doctorate in molecular genetics from the University of Texas at Austin (Department of Microbiology), a Master of Science in immunology from the University of Oklahoma Health Sciences Center, Oklahoma City (Department of Microbiology and Immunology), and an Arts Bachelor in biology from the University of Missouri (Columbia). Her postdoctoral studies were conducted at the University of Texas M.D. Anderson Cancer Center in Houston, the University of South Carolina (Columbia), and the University of North Carolina-Chapel Hill / U.S. Environmental Protection Agency – Research Triangle Park.

Medical Countermeasures Discovery

Dr. Nathan Adams

Dr. Adams currently works as a civilian employee in the Transformational Medical Technologies Initiative (TMTI) within the Defense Threat Reduction Agency.
Prior to coming to DTRA, Nate worked in the fine chemicals, pharmaceuticals, and aerospace industries. He earned a Ph.D. in organic chemistry and an M.B.A. from Brigham Young University, Provo, completed a master's degree in biostatics at the University of Utah, and carried out nearly four years of postdoctoral studies in pharmaceutics, also at the University of Utah. His wife, Marilyn, and he are the proud parents of two sons and a truly exceptional daughter.

David Klaasse

Mr. David A. Klaasse currently manages the TMTI Technologies Portfolio. The Technologies Portfolio consists of forty projects with the goal of developing platform technologies to support rapid response to an attack by an emerging or genetically engineered biological agent. Prior to joining DTRA, Mr. Klaasse served over 20 years in the US Navy. While in the Navy, Mr. Klaasse flew aircraft carrier based F-14 "Tomcats" on numerous overseas deployments including combat operations in Operations Desert Storm, Desert Strike and Southern Watch. Between deployments, he graduated from the Navy's Fighter Weapons School (Topgun) and the US Naval Test Pilot School. Joining the Navy's acquisition corp, Mr. Klaasse managed Integrated Product Teams within the National Reconnaissance Office and the F-35 Joint Strike Fighter Program Office. Mr. Klaassee joined TMTI shortly after retiring from the US Navy in 2008.

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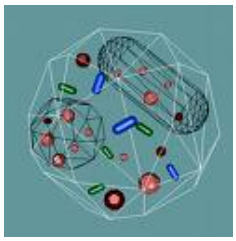
Break Out Session 3 (Pegasus A)
(Moderator: Weaver)

Time	Event	Speaker
	Bioinformatics	
1330-1335	**Overview and Introduction** *Dr. Randall Kincaid, Scientific Director of TMTI*	**Dr. Kincaid**
1335-1345	**TMTI and Bioinformatics** *Mr. Greg Meyers, TMTI Subject Matter Expert*	**Mr. Meyers**
1345-1405	**Turning TMTI Genome Sequence into Countermeasure Targets** *Dr. Victor Pollara, Senior Principal Scientist, Noblis, Inc*	**Dr. Pollara**
1405-1425	**Bounding the TMTI Bioinformatics Architecture** *Dr. Tom Slezak, Associate Program Leader, Lawrence Livermore National Lab*	**Dr. Slezak**
1425-1440	**Break**	
1440-1540	**Group Discussion** • Are there new technologies or new use for current technologies (data bases, tools, data access)? • If you could develop a system without constraint, what would it look like? • Where do we get tools?	



Systems Biology

Time	Event	Speaker
1610-1615	**Introduction and Overview** *Dr. Randall Kincaid, TMTI Science Director*	**Dr. Kincaid**
1615-1640	**Host Pathogen Interaction and Immune Response** *Dr. Ronald Germain, Chief, Lymphocyte Biology Section, Laboratory of Immunology and Director, Program in Systems Immunology and Infectious Disease Modeling, NIAID*	**Dr. Germain**
1640-1705	**Toxicology and Identification of Critical Markers** *Dr. Melvin Andersen, Director, Division of Computational Biology, The Hamner Institute for Health Science*	**Dr. Andersen**
1705-1730	**Delivering Systems Biology Value Through Structured, Shared Scientific Knowledge** *Dr. Ramon Felciano, Chief Technology Officer and Vice President for Research, Ingenuity Systems, Inc.*	**Dr. Felciano**
1730-1740	**Break**	
1740-1815	**Group Discussion** • Panel members will field questions from the audience and discuss the implications of their presentations	

Break Out Session 2: Exploring the State of the Science and Identification of Gaps
Speaker Biographies

Bioinformatics

Randall L. Kincaid, Ph.D.

Dr. Kincaid is the Scientific Director of Transformational Medical Technologies Initiative (TMTI), Defense Threat Reduction Agency, and plays a key role in developing the research priorities of the program. Prior to taking this position, he was the President and CEO of Veritas, Inc., a biotechnology consulting company involved with biodefense and infectious disease that he founded in 1995. From 1993-1995, he established a hematopoietic discovery program at Human Genome Sciences in his role as its first Director of Cell Biology. Dr. Kincaid was a tenured faculty member at the National Institutes of Health from 1977-1993, where his work centered on intracellular signaling mechanisms in the immune system, and in other tissues, and the pivotal roles played by Ca^{2+} and cyclic nucleotides in regulating protein phosphorylation. He received his Ph.D. in Pharmacology from Stanford University in 1977, and his undergraduate degree in Biology, also from Stanford, in 1972.

Gregory Meyers

Gregory Meyers is a Senior Systems Analyst for Analytic Services, Inc. (ANSER), providing A&AS support to TMTI in the areas of pathogen characterization and bioinformatics areas. Prior to joining ANSER, Greg was a group Leader, DNA Services, Commonwealth Biotechnologies, Inc., where he oversaw laboratory operations and scientific program direction of molecular biology, DNA sequencing, and microbial forensic and diagnostic service areas, and Project Manager, Icoria, Inc. where he was responsible for all project management aspects of $55million agricultural genomics collaboration between Monsanto Inc. and Icoria. Greg received his BS degree from Virginia Tech in Biology, with an emphasis on microbiology, and his MS degree from VCU/MCV in Microbiology and Immunology.

Dr. Victor Pollara

Dr. Victor J. Pollara is a senior principal scientist at Noblis, Inc. He joined Noblis in 2003 and has worked in bioinformatics and text mining in the biomedical area. Before joining Noblis, he worked at the MIT/Whitehead Institute on the SNP project and the Human Genome Project, and later served as the lead scientist for Viaken Systems, Inc., a bioinformatics infrastructure provider. He is currently providing bioinformatics infrastructure design support to the TMTI project. His academic background includes life sciences and mathematics, and his doctorate is in the area of theoretical computer science.

Dr. Tom Slezak

Tom Slezak, Associate Program Leader, Informatics, Lawrence Livermore National Lab (LLNL),has been involved with bioinformatics at LLNL for 30 years after receiving BS and MS degrees in Computer Science. Tom is currently the Associate Program Leader for Informatics for

the Global Security Program efforts at LLNL. He was involved with the Human Genome Program from 1987-2000, leading the informatics efforts at LLNL and then the DOE's Joint Genome Institute from 1997-2000. In 2000 he began to build a pathogen bioinformatics team at LLNL pioneering a novel whole-genome analysis approach to DNA signature design. His team developed signature targets for multiple human pathogens that were used at the 2002 Winter Olympic Games under the BASIS program and later adapted for use nationwide in the CDC's BioWatch program. Under a close collaboration with the CDC, the LLNL team has been called on for computational help on smallpox, SARS, monkeypox, avian influenza, and numerous other pathogens. In addition to continuing work on human and agricultural pathogens, Tom's team is currently focusing on signatures of mechanisms of virulence, antibiotic-resistance, and evidence of genetic engineering, utilizing high-density synthesized microarrays and genomic sequence. They have been focusing on detecting novel, engineered, and advanced biothreats for several years, under ITIC and DHS/NBACC funding. In 2009, the team has begun working on systems studies for the DTRA Transformational Medical Technology Initiative (TMTI). Tom has chaired or served on multiple advisory boards, including the rice genome project, mouse and maize genetics databases, the spruce tree genome project (Canada), plant pathogens, and a NIAID sequencing center contract renewal. He is currently serving on a National Academy panel focusing on scientific advancements needed to move the Select Agent program from an organism-based definition to a gene-based one.

Systems Biology

Randall L. Kincaid, Ph.D.

See description above

Ronald N. Germain, M.D. Ph.D.

Dr. Germain is the Chief, Lymphocyte Biology Section, Laboratory of Immunology and Director, Program in Systems Immunology and Infectious Disease Modeling
National Institute of Allergy and Infectious Disease, National Institutes of Health.

Dr. Germain is a tenured investigator at the National Institutes of Health and a principal member of its emerging efforts in the area of systems biology and human disease. He came to the NIH in 1982 and has contributed broadly to the areas of MHC-antigen recognition, T-cell signaling and

T-cell development for over 25 years. Prior to coming to the NIH in 1982, he was on the faculty of Harvard Medical School, where he was an Assistant and later Associate Professor of Pathology. Dr. Germain received his M.D. (magna cum laude) and Ph.D. from Harvard University in 1976 where he worked with B. Benacerraf, recipient of the 1980 Nobel Prize in Physiology and Medicine. He received his undergraduate degree in Biology (summa cum laude) from Brown University in 1970.

Melvin E. Andersen, Ph.D.

Dr. Andersen, Director, Division of Computational Biology, The Hamner Institute for Health Sciences, is a member of the Hamner Institute faculty, and heads up their innovative Program in

Chemical Safety Sciences, which addresses drug and environmental toxicants. He has advanced the use of computational methods that support pharmacokinetic / pharmacodynamic modeling

and created curricula that aid in health risk assessment; these efforts have attracted the attention of numerous organizations (OECD, EPA, FDA) for whom such work is highly relevant. He as held U.S. government positions in toxicology research and research management in the DoD and EPA and served as Professor of Environmental Health at Colorado State University from 1999-2002. Dr. Andersen received his Ph.D. in biochemistry and molecular biology from Cornell University in 1971. He received his undergraduate degree in Chemistry from Brown University in 1967.

Ramon M. Felciano, Ph.D.

Dr. Felciano, Chief Technology Officer and Vice President for Research, Ingenuity Systems, Inc., is a founding member of Ingenuity Systems, a knowledge-based technology enterprise that supports pathways analysis and other life sciences needs through its proprietary software solutions. In his role as Chief Technology Officer, he has helped to create an architecture that allows information to be searched efficiently and integrated into a visual framework that aid scientific analysis and prediction. Dr. Felciano started Ingenuity in 1998, while a graduate student in Biomedical Informatics at Stanford University and subsequently received his Ph.D. in 2000. Between 1990-1994, he also founded Digital Alchemy, a design and consulting firm, and co-founded SUMMIT, the Stanford University Medical Media and Information Technologies lab . He received his undergraduate degrees in English and French literature (1989) and in Computer Science, also from Stanford, in 1990.

TMTI Industry Day
Dallas Texas
19 November 2009

How to do Business with TMTI (Pegasus B)

(Moderator: Weaver)

Time	Event	Speaker
0900-1000	**Doing Business with TMTI** *Mr. Brian Reinhardt, TMTI Business Director* • Government rules and regulations affecting contracting • Solicitations: Process and format • Negotiations: How contracts are negotiated • Contracts: How an idea becomes a contract, how proposals are evaluated and process forward after a contract is signed • The end: Contract closeout procedures	**Mr. Reinhardt**
1000-1030	**Defense Contract Audit Agency (DCAA) and TMTI Contracts** • How to create an accurate accounting system • DCAA audits and requirements	**Ms. Chanay** **Ms. Young**
1030-1050	**Break**	
1050-1200	**Performer Panel** • Each panel member will have 5 minutes to answer the following: 1. Who are they and what do they do? 2. What was one good experience with TMTI? 3. What one area needed the most patience? 4. What one thing would they do differently? **Panel Members: Dr. Pat Iversen** (AVI Bio Pharma) **Dr. David Payne** (GlaxoSmithKline) **Dr. Ze-Qi Xu** (Advanced Life Sciences) **Ms. Jana Young** (DCAA) **Ms. Kelley Chanay** (DCAA) **Ms. Terese Herston** (DTRA)	

Summary Session
Speaker Biographies

Mr. Brian Reinhardt

Brian Reinhardt is currently serving as the Transformational Medical Technologies Initiative (TMTI) Business Director for the Defense Threat Reduction Agency (DTRA) in Alexandria, VA. Prior to this position, Brian has served within DTRA as a Science and Technology Manager for TMTI, the Interagency Biological Restoration Demonstration, and the National Guard Weapons of Mass Destruction (WMD) Civil Support Team (CST) science and technology program.

Previous to his experience with DTRA programs, Brian served as a Field Artillery Battery Executive Officer, Platoon Leader and Fire Direction Officer in the 1st Infantry Division (US Army), Germany. While stationed in Germany, Brian was part of two NATO deployments under Stabilization Force (SFOR), Bosnia and Kosovo Force (KFOR), Serbia.

He received a Bachelor of Science degree in Chemistry from the University of Oklahoma, a Master of Science in Natural Product Synthesis from Kansas State University, and a Master of Science in Synthesis using Enantioselective Catalysis from Georgetown University. He is a member of the Phi Lambda Upsilon Chemical Honor Society and the American Chemical Society. His military awards include: National Defense Service Medal, Kosovo Campaign Medal, NATO Medal, Armed Forces Expeditionary Medal, Army Commendation Medal, Army Achievement Medal, Armed Forces Service Medal, Army Service Ribbon, Overseas Service Ribbon, Army Superior Unit Award, Parachutist Badge.

Dr. Pat Iverson

Patrick L. Iversen, Ph.D., Senior Vice President of Strategic Alliances, served as Senior Vice President of Research and Development from 1997 to 2008 (and a director from 1997 to 2007), assuming this new role in 2008. From 1987 through 1997, he was on the staff of the University of Nebraska Medical Center. Dr. Iversen has published extensively on antisense research and development, and has been a consultant to companies including Glaxo Inc., Innovir Pharmaceuticals, Lynx Therapeutics, and Isis Pharmaceuticals.

Dr. David Payne

Dr Payne, Vice-President, Antibacterial Discovery Performance Unit, GSK, USA, holds a BSc in Biochemistry from Brunel University, UK, and a PhD and DSc from The Medical School, University of Edinburgh, UK. Dr Payne has worked for GSK for 18 years and is currently Vice President and Head of the Antibacterial Discovery Performance Unit (DPU) within the Infectious Diseases Centre of Excellence in Drug Discovery (ID CEDD) where he is responsible for GSK's antibacterial research effort from discovery to clinical proof of concept (up to Phase II clinical trials).

At GSK, Dr Payne has played a leading role in redesigning the strategy for antibacterial research and has helped create long-term alliances with three innovative biotechnology companies (Anacor, Mpex, and Galapagos) which has expanded GSK's discovery pipeline. Furthermore, he

has created industry-leading partnerships with the Wellcome Trust and the Defense Threat Reduction Agency (US Department of Defense) to accelerate one of GSK's antibacterial programmes.

To date, Dr Payne has been involved with the progression of several novel antibacterial agents into Phase I clinical trials and has played a major role in the discovery and development of Altabax/Altargo (the first novel topical antibiotic launched in the last 20 years).

Dr Payne has given >100 conference presentations and published more than 90 papers.

Dr. Ze-Qi Xu

Dr. Ze-Qi Xu, Chief Scientific Officer & EVP, Advanced Life Sciences, Inc., Woodridge, IL, received his PhD in Organic Chemistry from the Chinese Academy of Sciences (Shanghai, China) and received his post doctoral training at the Michigan Cancer Foundation (Detroit, Michigan) and at Clemson University (Clemson, South Carolina). Ze-Qi Xu has an undergraduate degree in Chemistry and an M.Sc. in Medicinal Chemistry. Dr. Ze-Qi has more than 25 years of research experience within a broad spectrum of biomedical sciences including organic chemistry and medicinal chemistry. Additionally, he has more than 15 years of increasingly responsible research, development and operating management positions in the pharmaceutical industry. Dr. Xu has been awarded more than $5 million in research grants from various state and federal government agencies.

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Capability Briefs (Gaston A & B)
(Moderators: Weaver and Moore)

Time	Event	Speaker

PLEASE NOTE:
THESE ARE CLOSED SESSIONS

Individual schedules set by agreement between TMTI and participant
Schedules may be verified with the TMTI Industry Day booth

1300-1730	**Gaston A - Medical Countermeasures Portfolio**
1300-1730	**Gaston B - Technologies Portfolio**